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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/869,275	06/04/1997	CARL T. WITTWER	T8616.CIP5	5556

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INDIANAPOLIS, IN 46204

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/869,275	WITTWER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 126, 127, 141, 142, 149, 150, 153, 189 and 190 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>(1 copy)</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>(1 sheet)</u> . | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 9/15/03, has been entered.

Applicants' arguments, filed 9/15/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **VAGUENESS AND INDEFINITENESS**

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The antecedent basis for the volume limitation in claim 18 of not greater than 10,000 ul is not clear given the claim 13 sample volume container of less than 1 milliliter. Clarification via clearer claim wording is requested.

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-18, 20, 22-35, 55-59, 79, 80, 82, 87-92, 121-125, 128-132, 134-140, 143-148, 151, 152, 154-158, 160, 169-188, 191-195, and 197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouma et al. (WO 93/20240); taken in view of Jordan (P/N 4,325,910).

Priority is not granted for the instant claims to the earliest parent application serial numbers 07/534,029 and 07/815,996 because these applications do not provide written support for the instant claim limitations directed to a rotatable carousel nor simultaneous cooling or heating of sample containers in such a carousel nor moving each sample one by one to a monitoring position via said carousel. Thus, both Bouma et al. (WO 93/20240) and Jordan (P/N 4,325,910) are prior art to the instantly claimed invention.

Bouma et al. describes amplification of analytes such as nucleic acids in the abstract. In the section entitled "C. Reagents and Protocols" on pages 10-12, Bouma et al. further describes the reagents and protocols for amplification via PCR with it attendant temperature cycling between heated and cooled time segments therein as

also instantly claimed as a characteristic of the claimed system. Fluorescence measurement of sample cuvettes is described on page 4, lines 12-20, with excitation of reaction samples for that purpose. Thermocycling via air baths as well as the small sample reaction vessels as instantly claimed are described on page 8, lines 9-33. The PCR thermocycling is reasonably performed in a system via a temperature cycle time reaction parameter and adjusted for the desired time period as require in instant claims 14-16. On page 8, lines 25-33, the reaction vessels are described as being optically transparent which is reasonably interpreted to be the "optically clear" characteristic in instant claim 13, line 4, of sample containers. The reaction vessels on page 8, lines 14-20, are described as being typically a microcentrifuge tube but other configurations are suggested as being possible. It is also noted that certain instant claims have cooling and/or heating rates therein which are deemed reasonable characteristics of the small sized reaction vessels of Bouma et al. Bouma et al. lacks description of a carousel arrangement for sample positioning as instantly claimed.

Jordan summarizes its disclosure in the abstract as providing for multi-analysis of samples with reagents in reaction vessels providing also for fluorometry detection thereof. Figures 1 - 9 depict multiple sample carousel arrangements for reaction monitoring. The automation of laboratory procedures for increasing productivity and reducing error is a motivation to utilize the invention of Jordan set forth in column 1, lines 6-10, and column 3, lines 21-51. In column 3, line 66, through column 4, line 17, samples are optionally placed in photometer system measurement position via varying protocols as desired which describes the one by one monitoring positioning as instantly

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claimed. Jordan further describes whole device selected temperature control including vessels as described therein in column 18, lines 18-25, which describes the whole carousel simultaneous temperature control of the system as instantly claimed.

Temperature control in Jordan is not limited to a constant temperature but is inclusive of temperature change such as cooling as described in column 18, lines 26-30, albeit therein directed to diminishing reagent degradation. These descriptions reasonably indicate that the automatic system of Jordan may be utilized and is capable of temperature changing environmental control as desired and selected. As noted above a reaction performed for PCR requires controlled cycling of temperature. It was noted above that Bouma et al. suggested and motivated other shapes to the reaction vessels other than a microcentrifuge tube which is understood to be circular. In Jordan in column 14, lines 38-61, particularly in lines 55-56, the cuvette is described as having an exit side which supports another side as an entrance side wherein the cuvette contains reaction liquid/mixture and thus also has a bottom end as required in instant claim 13, lines 5-6.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to assemble the PCR system of Bouma et al. with the motivated and suggested multi-sample improvements of Jordan to result in the practice of the instant invention wherein the above descriptions provide a reasonable expectation of success in such system assembly.

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### CLAIM OBJECTIONS

Claims 126, 127, 141, 142, 149, 150, 153, 189, and 190 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants are requested to clarify the absence of listing claim 159 in the claim set, filed 9/15/03.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 27, 2005

*Ardin H. Marschel* 6/27/05  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**

**Continuation of Disposition of Claims:** Claims pending in the application are 13-18,20,22-35,55-59,79,80,82,87-92,121-132,134-158,160,169-195 and 197.

**Continuation of Disposition of Claims:** Claims rejected are 13-18,20,22-35,55-59,79,80,82,87-92,121-125,128-132,134-140,143-148,151,152,154-158,160,169-188,191-195 and 197.